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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,925	06/20/2001	Seiichi Araki	MTSU-1001US	7925
21302	7590	01/10/2006	EXAMINER	
KNOBLE, YOSHIDA & DUNLEAVY EIGHT PENN CENTER SUITE 1350, 1628 JOHN F KENNEDY BLVD PHILADELPHIA, PA 19103			DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/806,925	Applicant(s) ARAKI ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 153,156-162,166,167,183,185-194 and 196-210 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 153,156-162,166,167,183,185-194 and 196-210 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment and response filed October 24, 2005 has been received and entered into the case. Claims 154-155, 163-165, 168-182, 184 and 195 are canceled; claims 205-210 are added; claims 153, 156-162, 166-167, 183, 185-194, 196-210 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 153, 156-162, 166-167, 183, 185-194, 196-210 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification as originally filed in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the phrase "containing less saccharides" is not described in the specification as originally filed. While the specification does disclose fractions of sugar cane that contain sucrose, fractions with "less sucrose" or "less sugar", the specification fails to describe a fraction that contains "less saccharides". This is a new matter rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 153, 156-162, 166-167, 183, 185-194, 196-210 are rejected under 35 U.S.C.

103(a) as being unpatentable over Bermudez, Kawai, Saska, Agar, Brewer and Kearny.

Applicant claims a method for remedying a disease caused by an infection in humans or animals, the method comprising orally administering an effective amount of sugar cane derived extract in an amount to remedy the disease, wherein the infection is E. coli, or pseudorabies; wherein the extract is obtainable from a variety of steps; and wherein the sugar cane extract contains less saccharide than the raw material, or original material. Specifically, the sugar cane extract is obtainable by passing a raw material selected from sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses through a column packed with a synthetic adsorbent as the fixed carrier, eluting with water, methanol, ethanol, or mixtures thereof. Alternatively, the extract is a fraction absorbs light at a wavelength of 420 nm and is obtainable by column chromatography using an ion exchange resin packed in a column. The ion exchange resin is a cation resin, is a strongly acidic cation exchange resin, is a sodium or potassium form, or is a gel resin. The ion exchange is carried out in a pseudo moving bed continuous separation, and the fraction is further treated with electrodialysis. The sugar cane extract is in the form of a food or animal feed. Applicant claims the method wherein the sugar cane extract has a MW of

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less than 1000. Applicant additionally claims the method wherein the extract is administered via oral, IV, intramuscular, subcutaneous, intra-abdominal, intrarectal, hypoglossal, or instillation routes.

Bermudez teaches methods for treating bacterial and viral infections, the method comprising administering effective amounts of sugar cane extracts (abstract, p.2,4). The extracts are obtained from sugar cane and are fractionated/purified with column chromatography (p.10), and are administered orally, topically, intrarectally, enterally, IV, intramuscularly and/or inhalation (p.6). Bermudez teaches the fractionation and purification can be accomplished by known methods in the art, including chromatography, ion exchange, lipophilic or hydrophobic resins. Bermudez further teaches that the fractions are typically analyzed for their physical-chemical nature, to include MS, laser desorption, infrared, ultraviolet, visible spectrometry and high-resolution nuclear magnetic resonance spectrometry (p.10). Although Bermudez does not teach the extract has a MW of less than 1000, the method steps appear to be the same, therefore the product also appears to be the same. Therefore the extract of Bermudez must also have the claimed MW.

Bermudez does not teach each of the claimed limitations drawn to the specifics of the fractionation, purification and analysis. However, Bermudez clearly teaches that known methods in the art are used. At the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to obtain the sugar cane extracts of Bermudez via the claimed methods, because they were routinely practiced in the art. In support, Kawai teaches methods for extracting sugar cane wherein sugar cane juice or sugar cane derived molasses is treated with column chromatography packed with a synthetic adsorbent as a fixed carrier, eluted

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with water, methanol, ethanol or mixes thereof (abstract). The extracts are eluted with a mixed solvent of ethanol and water in a ratio of 50:50 to 60:40 (0017). The material is used in foods, feeds and medicines (0001). Further purification of the sugar cane extract is accomplished with ion exchange resins (0020), cation exchange resins (0021) and gel resins (examples). Kawai teaches that the obtained sugar cane extract can be used in foods, feed, and medicines (0031-0032). In addition, Saska teaches processes wherein sugar juice, or sugar derived molasses is treated with a strong cation exchange resin, in the form of sodium and/or potassium (abstract) and the eluted with water (col.2 line 21-29). Agar teaches methods for pulping plant materials such as bagasse (sugar cane extract), wherein extracts are recovered by treating the material with organic solvents (alcohol) (col.1 line 21-34, col.16 line 15-20), specifically with 60% ethanol and 40% water (col.4 line 24-26,35-50). Brewer teaches known methods for producing extracts of sugarcane using ion exchange, strongly acidic ion exchange resins (col.2 line 12-22), cations resins of the sodium form (col.2 line 33-39), and electrodialysis (col.3 line 8-10). Finally, Kearney teaches typical separation techniques of sugar extracts include ion exchange resins, continuous simulated moving bed systems (col.1 line 30-50). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practices to obtain the sugarcane extract of Bermudez as claimed, since they well known procedures, as evidenced by the cited references.

It is noted that if the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process,

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rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper (MPEP 2113). Although the instant claims are drawn to a method, the method merely comprises administering such a product by process.

Bermudez does not teach the method wherein the infections are caused by E. coli or pseudorabies. However, the reference does teach the extract can be used against a variety of different bacterial and viral infections. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Bermudez to treat the instant infections, as the extract was taught to be effective in treating bacterial and viral infections.

Response to Arguments

Applicant argues that the references do not teach administration of sugar cane extracts, that the extracts are made differently, that the instant claims do not require heat polymerization to make the extract as in the art, and argues the references individually.

However, these arguments fail to persuade because the instant claims do not require that the extract be obtained in the manner claimed, but that it is *obtainable* by the claimed methods. Thus, the claims do not absolutely require that the product must be obtained by any particular process.

Regarding the supporting references, each of the cited references teach various processes for extracting sugar cane which are all well known in the art. Bermudez teaches that any normal method for processing sugar cane can be used in the making of the effective composition. Thus,

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one of ordinary skill in the art would certainly have been motivated by Bermudez to process sugar cane in the claimed methods, since they were well know and practiced methods as evidenced by the cited supporting references. Moreover, it appears that applicant practices known and used processes to extract sugar cane to obtain a product that can be used in the methods of Bermudez.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

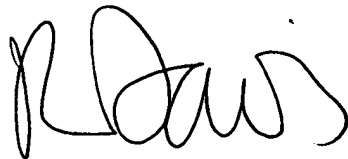
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
January 3, 2006
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A handwritten signature in black ink, appearing to read 'R. Davis', is positioned to the right of the typed name and date.